REMARKS

Reconsideration of the application is respectfully requested.

I. Status of the Claims

Claims 4-7 were previously canceled, without prejudice or disclaimer of the subject matter contained therein.

Claim 9 was found by the Examiner as being drawn to an unelected invention as defined by a previous restriction requirement, and was previously withdrawn.

Claims 1-3, 8, and 9 are pending and stand rejected and are presented as a courtesy to the Examiner.

II. Specification

The Examiner objects to the specification as failing to provide proper antecedent basis for the claimed subject matter. The Examiner states that the specification does not teach which of the variables and equations disclosed on pages 12-30 of the specification corresponds in Claim 8 to the claimed second measurement value, the second theoretical value, the difference between the second measurement value and the second theoretical value, the adjusted blood flow rate, and the second predetermined acceptable ration difference.

Applicants disclose, in support of claim 8, performing separate sets of measurements and calculations in determining the location of abnormal behavior in the device. A first set of measurements and calculations are performed determining if there

is a problem in the blood pump (or ultrafiltration pump) and a second set of measurements and calculations are performed to determine if such a problem exists in the opposite pump, utltrafiltration pump in this example (or blood pump). Support can be found in the specification as filed at page 12, lines 24 to page 16, line 5. For example, the device will keep the ultrafiltration pump at a preset level and adjust the blood pump, as a first adjusted flow rate, and perform a first set of measurements and calculations. This would then be followed by a second set of measurements and calculations where, for example, the blood pump would be held at a preset level and the ultrafiltration pump adjusted, as a second adjusted flow rate.

Furthermore, Applicants disclose a second embodiment that includes a plasma absorption device. Utilizing this device and maintaining appropriate behavior operates in a similar fashion as described above with a first set of measurements and calculations followed by a second set while utilizing the plasma absorption device. Support can be found in the specification as filed at page 33, lines 1-16, and at page 34, line 19 to page 35, line 4.

III.   **Rejections under 35 U.S.C. §103**

The rejection of Claims 1 - 3 and 8 under 35 U.S.C. §103(a) as being unpatentable over Brugger et al., US. Patent No. 6,554,789, ("Brugger"). The Examiner asserts that the requirement for the use of two separate ratios, as claimed by the Applicants, is essentially a requirement that the evaluation of the measurements obtained by the hematocrit sensors be done indirectly through ratios, rather than directly through

evaluation of the hematocrit data itself or indirectly through the use of some other suitable mathematical formula, as described by Brugger.

However, Applicants disclose the use of a **theoretical ratio value** calculated from data measured directly from the blood pump and blood purifier. A feature of the present invention is to detect mal-operations of the blood pump and fluid removal pump of the hemofiltration machine and further determine which pump is in mal-operation. The hematocrit level (Ht) indicates the volume occupied by red blood cells in the blood stream. Red blood cells are not discharged from dialyzer to an outlet side but are returned entirely to the body. Therefore, in the dialyzer, the rate at which blood cells flow upstream (blood flow per hour) corresponds to that flowing downstream. Thus, the following equation is derived:

Hta (theoretical value) x Qbin (set value) = Htv (theoretical value) x {Qbin (set value) – Quf (set value) }

Which is transformed to:

Hta (theoretical value) / Htv (theoretical value) = 1 – Quf (set value) / Qbin (set value).

To indicate actual behavior conditions, the measured value of Ht is used: Hta (measured value) / Htv (measured value) = 1 – Quf (actually worked value) / Qbin (actually worked value)

Then, whether {Hta (theoretical value) / Htv (theoretical value)} corresponds to

{Hta (measured value) / Htv (measured value)} is determined to be consistent (blood

pump and fluid removal pump behave normally) or inconsistent (either of them does not

behave normally). If either of them behave abnormally, the following equation (1) is

derived:

$$1 - Quf \text{ (set value)} / Qbin \text{ (set value)} \neq 1 - Quf \text{ (actually worked value)} / Qbin$$
$$\text{(actually worked value)}$$

(1) $\{Quf \text{ (set value)} / Qbin \text{ (set value)}\} / \{Quf \text{ (actually worked value)} / Qbin$

$\text{(actually worked value)}\} = p \quad (p \neq 1)$

Further, to determine if the blood pump behaves abnormally, for example, Qbin (set

value) is multiplied by x and Qbin (actually worked value) is multiplied by y, the

following equation is then derived:

(2) $\{Quf \text{ (set value)} / xQbin \text{ (set value)}\} / \{Quf \text{ (actually worked value)} / yQbin$

$\text{(actually worked value)}\} = (x/y) p \quad (p \neq 1)$

If the blood pump behaves normally, the result should be x=y, and the right-hand side of

(2) corresponds to the right-hand side of (1). If it does not correspond, the blood pump is

determined to be in mal-operation. By the same token, a mal-operation in the fluid pump

can be determined.

Whereas, <u>Brugger only utilizes actual measured data opposed to using theoretical</u>

<u>values for comparison purposes</u>. Brugger discloses a function to control FF to achieve a

desired value (set value), pre-treatment hematocrit value (Hti) and post-treatment

hematocrit value (Hto) are used (column 24, lines 21-23). FF is a desired percentage of

fluid to be removed from the bloodstream flowing through the hemofilter, which

corresponds to dialyzer (column 21, lines 42-43):

$$FF = UFR - BFR$$

Further, the following equation is derived by volume of bloodstream, preset stream

volume of waste, and volume of bloodstream which is returned to the venous

bloodstream:

$$UFR = BFR - RFR$$

On the other hand, red blood cells are not discharged but entirely returned to the body (by

the same is token as the invention claimed in the present application). The following

equation is derived:

$$BFR \times Hti = RFR \times Hto$$

Then it is transformed to:

(3) $$FF = (Hto - Hti) / Hto = 1 - Hti / Hto$$

By periodically comparing a desired FF, which can be preset or prescribed by an

attending physician (column 21, lines 43-44), with an FF which is derived by the

equation (3), a command is issued to make the difference between each FF become 0

(column 24, lines 32-33). Brugger balances the overall system by comparing FF, yet this

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value does not locate a mal-operation. Abnormal behavior is detected by sensors throughout the device (column 6, lines 53-63, column 7, lines 39-35, column 22, lines 47-51, and column 24, lines 35-45) and not through the calculations done within a evaluation unit.

Thus, the claimed invention would not be obvious over Brugger because using the evaluating unit to locate mal-operation is not a similar or an obvious variation of what Brugger discloses. The use of real data by Brugger is generally accepted as an ideal practice over using theoretical data, therefore one skilled in the art would not be taught or motivated to use theoretical values as disclosed in this application and present in the claims.

Accordingly, Applicants respectfully submit that Applicants' invention as claimed in independent claim 1 is neither anticipated nor made obvious by Brugger, and stands in condition for allowance. Claims 2, 3 and 8 depend from allowable independent claim 1 and, therefore, for the reasons noted above, are also considered to be in condition for allowance.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

The Examiner is respectfully requested to contact the undersigned at the telephone number indicated below if the Examiner believes any issue can be resolved through either a Supplemental Response or an Examiner's Amendment.

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